UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
BEAUMONT DIVISION

UNITED STATES OF AMERICA *ex rel.* BROOK JACKSON, Plaintiff, v. VENTAVIA RESEARCH GROUP, LLC; PFIZER, INC.; ICON, PLC Defendants.	Civil Action No.: 1:21-cv-00008-MJT

JOINT REPORT OF ATTORNEY CONFERENCE

Plaintiff-Relator Brook Jackson ("Relator"), on behalf of the United States of America, and Defendants Pfizer Inc. ("Pfizer"), Ventavia Research Group, LLC ("Ventavia"), and ICON plc[1] ("ICON") (collectively the "Parties") submit this Joint Conference Report pursuant to the Court's Order Setting Civil Action For Rule 16 Management Conference dated April 13, 2022 (ECF 31) ("Order").

The Parties met and conferred on May 3, 2022 and May 16, 2022 to discuss the topics enumerated in the Court's Order. The Parties were able to reach agreement on most issues. Where the Parties were unable to agree, they prepared separate statements in support of their respective positions, which are summarized below.

[1] By submitting this Joint Report of Attorney Conference, defendant ICON plc does not waive, and specifically preserves, its rights to assert any and all defenses in this matter, including, but not limited to, lack of personal jurisdiction.

1. A brief factual & legal synopsis of the case.

Relator's Statement: Relator Brook Jackson ("Relator") is a Clinical Research Auditor and Certified Clinical Research Professional who has worked in the pharmaceutical clinical trial field for years. During her career, she has been responsible for overseeing legal and regulatory compliance, adherence to good clinical practices, submission of required documentation, and business development. Relator began working for Defendant Ventavia as a Regional Director on September 8, 2020. Ventavia was contracted by Defendant Pfizer to provide three Phase 3 test sites in Houston, Fort Worth, and Keller, Texas for the COVID-19 vaccine co-developed by BioNTech SE and Pfizer. Pfizer delegated management of the clinical trials to subcontractor Defendant Icon, an Irish clinical research organization that was tasked with oversight of over 160 test sites worldwide.

As Regional Director of Ventavia, Relator oversaw site managers, patient recruitment success, training completion, quality assurance completion, enforcement of communication paths, and growth plans at two of Ventavia's three test sites for Pfizer-BioNTech's BNT162b2 vaccine clinical trial. Beginning on September 8, 2020, Relator reported to supervisors that patient safety and the integrity of the Pfizer-BioNTech vaccine trial were at risk after witnessing numerous clinical trial protocol and FDA regulatory violations. Violations that Relator witnessed include, but are not limited to: (1) enrollment and injection of ineligible trial participants; (2) falsification of data, poor recordkeeping, and the deficiency of Ventavia's documentation "quality control"; (3) deficiencies in and failure to obtain informed consent from trial participants; (4) adverse event capture and reporting; (5) failure to preserve blinding; (6) vaccine dilution errors; (7) failure to list all staff on delegation logs; (8) principal investigator oversight; (9) reporting temperature excursions; (10) patient safety issues, such as not keeping epinephrine dose information in patient

charts; (11) failure to secure and record staff training required by clinical research standards; (12) use of unqualified staff as vaccinators; (13) use of biohazard bags for needle disposal; and (14) failure to properly monitor patients post-injection. (Am. Compl. ¶ 23). She communicated these identified issues, many of which were systemic, to her supervisors both verbally and in writing on numerous occasions, but the identified problems were never addressed, and Relator was met with harassment and hostility. On September 25, 2020, Relator reported the clinical trial violations and patient safety concerns she witnessed to the FDA's hotline. On the very same day, Relator was terminated from her position at Ventavia in retaliation against her efforts to report and stop fraud against the United States Department of Defense ("DoD") resulting from the Pfizer-BioNTech COVID-19 vaccine trial.

Relator initiated this action with the understanding of the urgent task that Defendants had been given—to accurately evaluate the safety of the Pfizer-BioNTech vaccine, which has since become the most administered COVID-19 vaccine in the United States. Pfizer and Icon's oversight failures and fraudulent misconduct vis-à-vis Ventavia bring the entire Pfizer-BioNTech clinical trial into question. It was based on these fraudulent trials, which were deeply flawed and violated FDA regulations, that the U.S. Food and Drug Administration ("FDA") founded its authorizations and approvals. As a result of the first Emergency Use Authorization ("EUA") for the Pfizer-BioNTech vaccine issued on December 11, 2020, DoD paid billions of dollars to purchase these vaccines that it would not have paid had it known that the safety and efficacy of the vaccine at issue was not properly proven.

Relator brings her claims under the False Claims Act ("FCA"), claiming that Defendants Pfizer, Ventavia, and Icon 1) presented false and/or fraudulent claims to the United States for payment or approval, in violation of 31 U.S.C. § 3729(a)(1)(A); and 2) made or used false records

or statements that were material for false and/or fraudulent claims paid or approved by the United States, in violation of 31 U.S.C. § 3729(a)(1)(B). (Am. Compl. ¶¶ 292-304). Relator also brings a claim under 31 U.S.C. § 3730(h), alleging that Defendant Ventavia retaliated against Relator as a result of Relator's efforts to stop Defendants from committing FCA violations and punished Relator for her lawful and statutorily protected activity with harassment and termination. (Am. Compl. ¶¶ 306-309).

Pfizer's Statement: Pfizer manufactures one of three COVID-19 vaccines that FDA has authorized or approved since the onset of the pandemic. FDA first authorized Pfizer's vaccine for emergency use on December 11, 2020, and then fully approved it on August 23, 2021. These approvals were based on a "landmark" clinical study involving more than 40,000 clinical trial participants enrolled at 153 clinical research sites located in six countries. Pfizer contracted with a highly regarded clinical research organization, which is an affiliate of ICON, to help monitor and oversee the clinical trial sites. Ventavia owned and operated three of the 153 research sites involved in the landmark study and enrolled approximately 1,000 of the 40,000 trial participants. Relator worked as a Regional Director at two of the three Ventavia sites—both located in Tarrant County, Texas—from September 8, 2020 until September 25, 2020.

Relator brings this FCA action, alleging—in the face of a global pandemic that has claimed the lives of more than one million Americans—that FDA should not have approved Pfizer's vaccine, nor should DoD have paid for it, based on conduct she allegedly observed during her short tenure at Ventavia. (Am. Compl. ¶ 287). With respect to Pfizer, the complaint alleges the company violated certain FDA regulations requiring clinical trial sponsors to monitor clinical investigations, 21 C.F.R. §§ 312.50, 312.56, and certain provisions of the Federal Acquisition Regulation ("FAR") requiring government contractors to manage their subcontractors, 48 C.F.R. §§ 42-

202(e)(2), 52.203-13. (Am. Compl. ¶¶ 211-224.) According to Relator, these alleged regulatory violations "went to the very essence of the bargain" between Pfizer and DoD, (Am. Comp. ¶ 287), and resulted in "express and implied false certifications" of compliance in Pfizer's claims for payment to the Government (Am. Comp. ¶ 274). All of this, she alleges, violated Sections 3729(a)(1)(A) and 3729(a)(1)(B) of the FCA.

Both of these causes of action fail because Relator has not sufficiently plead—nor can she prove—that Pfizer submitted a "false or fraudulent" claim seeking payment from the Government. *See*, *e.g.*, *United States ex rel. Grubbs v. Kanneganti*, 565 F.3d 180, 188 (5th Cir. 2009) ("[T]he provision's *sine qua non* is the presentment of a false claim."); *United States v. Southland Management Corp.*, 326 F.3d 669, 675 (5th Cir. 2003) ("There is no liability under this Act for a false statement unless it is used to get [a] false claim paid."). Specifically, the complaint does not plead any false or misleading statements or representations that Pfizer submitted to the United States in the company's invoices for its vaccine, as required under the FCA. Relator instead focuses her complaint on purported violations of various federal regulations. These allegations are inadequate because, as the Supreme Court has stated repeatedly, the FCA is "not an all-purpose anti-fraud statute," nor is it "a vehicle for punishing garden-variety breaches of contract and regulatory violations." *Universal Health Services, Inc. v. United States ex rel. Escobar,* 579 U.S. 176, 194 (2016) (quoting *Allison Engine Co. v. United States ex rel. Sanders,* 553 U.S. 662, 672 (2008)); *see also United States ex rel. Thompson v. Columbia/HCA Healthcare Corp.,* 125 F.3d 899, 902 (5th Cir. 1997) ("Violations of laws, rules, or regulations alone do not create a cause of action under the FCA.").

At best, Relator's complaint represents a deficient attempt to state a cause of action under the "implied false certification" theory of FCA liability. Claims for payment can be impliedly

"false" under that theory when, among other things, they fail to disclose noncompliance with statutory, regulatory, or contractual requirements that are "material to the Government's payment decision." *Escobar,* 579 U.S. at 192. This materiality standard is a "demanding" one—not "too fact intensive" to decide on a motion to dismiss—that "looks to the effect on the likely or actual behavior of the recipient of the alleged misrepresentation." *Id.* at 194, 195 n.6.

The Government's "actual behavior" here says it all. Both the complaint itself and the public record show the Government has been fully aware of Relator's allegations for nearly two years without withdrawing authorization or stopping payment for Pfizer's vaccine. To the contrary, FDA took regulatory action that made the vaccine widely available and publicly responded to Relator's allegations by expressing the agency's "full confidence" in the data used to support the vaccine. DoD continues to purchase the product and make it available, free of charge, to all people living in the United States. And the U.S. Department of Justice ("DOJ"), which was required under 31 U.S.C. § 3730(a) to investigate Relator's allegations "diligently," declined to intervene in this lawsuit. All of this is "very strong evidence" that Relator's allegations are not material to the United States. *Escobar,* 579 U.S. at 195 ("[I]f the Government pays a particular claim in full despite its actual knowledge that certain requirements were violated, that is very strong evidence that those requirements are not material.").

Setting aside the dispositive falsity and materiality questions, Relator's claim cannot proceed in this Court under the express terms of the agreement under which the Government started purchasing Pfizer's vaccine. That agreement contains detailed alternative dispute resolution ("ADR") procedures, which broadly apply to "[a]ny disagreement, claim or dispute among the [p]arties concerning questions of fact or law arising from or in connection with [the] Agreement and *whether or not involving an alleged breach of [the] Agreement*." (ECF 37, Exhibit

A § 7.02, ¶ 1.) In other words, the agreement's ADR requirements apply, under their plain terms, both to contractual and non-contractual causes of action, including statutory claims like the present FCA lawsuit. Only upon exhausting those ADR requirements may the Government pursue "any right or remedy provided by law." (ECF 37, Exhibit A, § 7.02, ¶ 4.) But the Government has not pursued ADR or taken any other action against Pfizer. And Relator, who stands in the shoes of the United States as a "partial assignee" of the Government's rights under the FCA, *Little v. Shell Expl. & Prod. Co.,* 690 F.3d 282, 285 (5th Cir. 2012), cannot sue Pfizer on the Government's behalf unless and until the Government first satisfies the ADR requirements that it undertook when it contracted to purchase Pfizer's vaccine. *See United States v. Bankers Ins., Inc.,* 245 F.3d 315, 324 (4th Cir. 2001) ("The Government should comply with its contract obligations, and it cannot avoid them merely by invoking a statutory civil claim, such as one contemplated under the FCA."); *see also Arcadis U.S., Inc. v. Stryker Demolition & Env't Servs., LLC,* No. 20-0471, 2021 WL 785138, at *3 (W.D. La. Mar. 1, 2021) ("The consensus among district courts is that failure to mediate a dispute pursuant to a contract that makes mediation a condition precedent to filing a lawsuit warrants dismissal under Rule 12(b)(6).").

For all of these reasons, Pfizer has moved to dismiss Relator's claims. (ECF 37.)

Ventavia's Statement: Ventavia is a leading clinical research firm, specializing in clinical trials of pediatric, maternal, and adult vaccines and other medicines. Ventavia and the other defendants in this case were part of a modern miracle: the rapid development of a life-saving vaccine for a novel coronavirus during a raging pandemic. This extraordinary achievement required unprecedented effort from countless individuals, including the need to conduct clinical vaccine trials at hundreds of test sites as quickly and safely as possible.

As discussed above, Pfizer enlisted Ventavia and others to help conduct the vaccine trials.

Relator worked for Ventavia for just 18 days. Once hired by Ventavia, Relator immediately began to secretly record phone calls with staff members—asking for detailed information about any staff concerns with the company. To the extent she focused on the trials at all, Relator made vague insinuations about the conduct of the trial and generally refused to comply with multiple requests from the Ventavia leadership team to document and share her concerns in detail. When she finally shared a few concerns, they had either already been addressed, were in the process of being addressed, or were found to be untrue. Relator's behavior became even more concerning when her secret late-night searches through the facility ended up unblinding Relator in the trial—a concern she now directs toward Ventavia. Relator then unblinded her own manager. Ultimately, Relator's entire goal appeared to be to take bits and pieces of information and create a narrative that furthered her desires to scare the public, achieve some sort of fame, and win a huge payout.

Relator has now filed this lawsuit, ostensibly on behalf of the United States, claiming that Ventavia did not perfectly follow Pfizer's testing rules for every trial participant. Relator then extrapolates from those alleged violations—while admitting she was only exposed to a few patients from trial sites that represented a tiny sliver of the overall Phase 3 trial (.03%, per Relator's overstated allegations)—to allege a far-reaching theory that the Government was wholly defrauded in its purchase of Pfizer's COVID-19 vaccines.

But the Government does not think it was defrauded. It has known about these allegations for nearly two years and says it would have bought the vaccines anyway. Indeed, the Government has continued to approve and purchase Pfizer's vaccine—because it saves lives. The Government also declined to join this litigation. Because Relator purports to bring her claims on behalf of the Government, those facts should be the end of the case. But Relator's claims fail for several other independent reasons: (1) Relator has not sufficiently alleged the details of any false claims for

payment to the Government; (2) even if Relator could show that the alleged protocol violations rendered some claims for Government payment false, her lawsuit would still fail because the alleged violations were immaterial to the Government's payment decisions; and (3) Relator has not sufficiently alleged (because she cannot) that Ventavia itself violated the FCA—meaning the FCA claims against Ventavia must be dismissed at a minimum.

Relator's retaliation claim also fails for several reasons. While her fundamental allegation is false as a matter of fact—Relator was fired for violating company protocols and patient confidentiality, not for raising red flags about the clinical trial—the retaliation claim fails even the most basic pleading burden. The FCA's retaliation provision applies only when the relator has engaged in protected activity by reporting concerns about Government fraud, not just concerns about regulatory violations. Relator only attempts the latter. Nor does she allege that Ventavia *knew* that she was concerned about Government fraud. Both deficiencies are independently fatal.

The FCA is supposed to be a tool for rooting out Government fraud, not amplifying a publicity-seeking smear campaign. Relator's audacious conspiracy theory—that three separate parties (Ventavia, Pfizer, and ICON), along with the federal government, are attempting to trick the American public into taking a vaccine—is dangerous, unsupported, and unworthy of this Court's attention. Relator's complaint should be dismissed, in full, with prejudice. For these reasons, among others, Ventavia will move to dismiss Relator's claims.

ICON's Statement: Relator's amended pleading confirms that the claims against ICON plc ("ICON") are at most an afterthought that find no factual or legal support in the allegations. The allegations against ICON are sparse and come nowhere near stating a plausible claim. In addition to the points raised by Pfizer above—with which ICON agrees—Relator only describes ICON as having "constructive notice" of alleged misconduct, based primarily upon the curious

assertion that ICON had access to information allegedly "hidden away" by Ventavia in "notes to the file" or source documents. (Am. Compl. ¶¶ 8, 169, 191). Despite acknowledging that her experience with test sites spanned mere days and "is limited to Texas," Relator claims that "Pfizer and ICON's oversight failures and fraudulent misconduct vis-à-vis Ventavia bring the entire Pfizer BioNTech clinical trial into question. It is likely that similar fraud occurred at clinical trial sites managed by other subcontractors of Pfizer." (Am. Compl. ¶ 11).

Relator's allegations against ICON fall far short of the standard established under Rule 9(b). *See United States ex rel. Steury* v. *Cardinal Health, Inc.,* 2011 WL 13266915, at *3, 6 (S.D. Tex. Aug. 29, 2011), *report and recommendation adopted*, 2011 WL 13266916 (S.D. Tex. Sept. 27, 2011) (holding that claims brought under the FCA must satisfy the heightened pleading requirements of Rule 9(b), a more strict standard than Rule 8). The small number of allegations against ICON are generalized, conclusory, or speculative, and cannot state a plausible claim consistent with Rule 9(b). For example, Relator alleges ICON missed "red flags" of trial protocol violations and that errors would have been obvious from source documents, but does not state with "particularity" which red flags ICON missed or how the violations were obvious from which documents. *Westbrook*, 751 F.3d at 365; *see also U.S. ex rel. Ruscher v. Omnicare, Inc.,* 2014 WL 2618158, at *9 (S.D. Tex. Jun. 12, 2014), *on reconsideration in part sub nom*. *Ruscheri v. Omnicare, Inc.*, 2014 WL 4388726 (S.D. Tex. Sept. 5, 2014) (holding that a relator who seeks to advance an FCA claim must provide factual content establishing the "who, what, where, when and how" as to each of the specific elements of the cause of action). In fact, Relator's Amended Complaint is littered with contrary allegations that information was purposefully withheld from ICON; a curiosity that demonstrates the frivolity of Relator's claims against ICON. (Am. Compl. ¶¶ 29, 150, 157, 161, 169, 176, 178, 183-84, 196-97, 201, 205, 251, 254).

Relator makes sparse allegations that are, if anything, suggestive only of lawful conduct, and do not state a plausible claim that ICON submitted a false statement or engaged in fraudulent conduct. Likewise, Relator makes a litany of conclusory allegations and says nothing alleging that ICON intended to make any false record or statement, let alone one material to the Government's decision to pay or approve a false claim. The Amended Complaint does not allege that ICON submitted any claim to the Government, facilitated any claim to the Government, or received any compensation from the Government. And as Pfizer's argument already establishes, there can be no quasi-contractual or "implied false claim" predicated upon a contract in any event, particularly here where the Government's continued conduct evidences a lack of materiality with regard to any allegedly false statements.

Relator also does not allege that ICON possessed the requisite knowledge of any alleged falsity and does not allege a conspiracy claim under the FCA. At most, Relator alleges that ICON had "constructive notice" or "constructive knowledge" of purported falsehoods, but this is not enough. *U.S. ex rel. Longhi* v. *United States*, 575 F.3d 458, 468 (5th Cir. 2009) (holding that "the Government must demonstrate the Defendants had (1) actual knowledge of falsity, (2) acted with deliberate ignorance of the truth or falsity of the information provided, or (3) acted with reckless disregard of the truth or falsity of the information provided"). To be clear, ICON disputes that there were any falsehoods made by Pfizer at all—and certainly none of which it could be aware—but pleading mere constructive knowledge of alleged falsehoods is insufficient to state a claim in any event.

For these reasons, among others, ICON will move to dismiss Relator's claims.

2. Jurisdictional basis for this suit.

Relator's Statement: None.

Defendants' Statement: This Court has subject-matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1345. Defendants Pfizer and Ventavia do not challenge personal jurisdiction or venue. Defendant ICON plc is an Irish company that is not subject to general jurisdiction in the United States, a fact tacitly acknowledged by Relator in her Amended Complaint. (*See* Am. Compl. at ¶ 45 ("Icon PLC ('Icon') is an Irish company headquartered in Dublin.") and ¶ 48 ("Icon may be served at South County Business Park, Leoparddstown, Dublin 18, Ireland.").) ICON plc also does not have a sufficient nexus to the United States to be subject to specific jurisdiction with regard to Relator's claims. ICON plc does not waive, and specifically preserves, its rights to assert lack of personal jurisdiction as a defense in this action.

3. Confirm that initial mandatory disclosures required by Rule 26(a)(1) and this Order have been completed.

On April 22, 2022, the Court entered an Order granting the Parties' Joint Motion Regarding Briefing Schedule, which directed that "[a]ll remaining litigation deadlines in this matter will be subject to the Court's Scheduling Order." (ECF 38.) Defendants will therefore serve their Initial Mandatory Disclosures as provided in the Court's forthcoming Scheduling Order. The Parties have attached a proposed Scheduling Order, which includes a proposed deadline for serving Initial Mandatory Disclosures, as Exhibit A to this Joint Report. Relator served Initial Disclosures on May 13, 2022.

4. Proposed Scheduling Order deadlines. Appendix 1 has the standard deadlines. Explain any deviations from standard schedule. Now is the time to inform the court of any special complexities or need for more time before the trial setting. The standard schedule is planned so that there is time to rule on dispositive motions before parties begin final trial preparation.

Relator's Position: Relator is opposed to Defendants' motions seeking to stay discovery and defer entry of a Scheduling Order (ECF 40, 41, 42). Relator does not otherwise object to the schedule attached as Exhibit A.

Defendants' Position: Defendants have moved the Court to stay discovery—and defer entry of a Scheduling Order—until the Court decides Defendants' motions to dismiss. (ECF 40, 41, 42.) For the reasons set forth in Defendants' motions to stay discovery and/or notice of joinder, Defendants believe that good cause exists to stay discovery, because, among other things, (1) Defendants have strong arguments for dismissal; (2) Relator's claims against Pfizer are subject to mandatory ADR requirements to which the United States agreed in its initial contract to purchase Pfizer's vaccine; (3) discovery in this case will be extensive and impose substantial burdens, not only on the parties, but also on several federal government agencies focused on fighting the COVID-19 pandemic; and (4) given Relator's history of violating this Court's sealing order to promote her anti-vaccination agenda, the Court should satisfy itself that Relator has stated a viable claim and that the Court's case management orders will be followed before discovery begins.

When and if discovery begins, Defendants believe a modest extension of the standard deadlines listed in Appendix 1 of the Order will be necessary to facilitate completion of essential discovery in light of the complex legal and factual issues presented by this case. This litigation will require extensive discovery, not only from the Parties, but also from multiple agencies of the Government with responsibility for authorizing and purchasing Pfizer's vaccine, as well as investigating Relator's allegations. Discovery will be needed at a minimum from FDA, DoD, and DOJ. Such discovery will be necessary before Defendants can complete all required depositions and expert submissions. A proposed case schedule is attached as Exhibit A to this Joint Report. As reflected in Exhibit A, Defendants believe the Court should defer entry of a Scheduling Order pending the Court's resolution of their motions to dismiss. Relator disagrees that a Scheduling Order should be deferred, but does not otherwise object to the schedule in Exhibit A.

5. If the parties agree that mediation is appropriate, and the parties can agree upon a mediator, the name, address, and phone number of that mediator, and a proposed deadline should be stated. An early date is encouraged to reduce expenses. The court may appoint a mediator upon request.

The Parties believe it is premature to consider whether mediation is appropriate and believe that mediation should be ordered, if at all, after the dispositive motion deadline set forth in the proposed Scheduling Order attached as Exhibit A.

6. What changes, if any, should be made to the limitations on discovery imposed by the rules, including number of depositions and interrogatories.

At this time, the Parties are not requesting any alterations to the discovery limitations provided in Federal Rules of Civil Procedure 26(b), 30, 31, 33, 34, and 36.

7. The identity of persons expected to be deposed.

The Parties are continuing the process of identifying persons expected to be deposed in this matter. Relator anticipates taking depositions of Relator and Ventavia management (Director of Operations Marnie Fisher; Executive Directors Olivia Ray and Kristie Raney; Chief Operating Officer Mercedes Livingston; Fort Worth Principal Investigator Dr. Mark Koch; Houston Regional Director Lovica Downs; Director of Quality Control William Jones).

Defendants anticipate taking depositions of Relator, Relator's former counsel, and assorted Government personnel. Relator's website and social media pages disclose both the existence and the substance of communications involving her former counsel and numerous FDA and DoD employees concerning the materiality of Relator's allegations to the Government's regulatory and payment decisions. Defendants are entitled to investigate these statements, which Relator has put

at issue through her decision to publish them to the world and they are central to a defense of this case.

Plaintiff and Defendants reserve their rights to take depositions during the discovery period in accordance with the limitations on discovery imposed by the Federal Rules and the Court's Scheduling Order.

8. Any issues relating to disclosure or discovery of electronically stored information, including the form or forms in which it should be produced.

The Parties have agreed to a proposed E-Discovery Order, which they have submitted as Exhibit B to this Joint Report.

9. Agreements Relating to Claims of Privilege, Preserving Discoverable Information, and Federal Rule of Evidence 502.

The Parties have conferred concerning reasonable and proportional steps to preserve relevant evidence. The Parties agree that a protective order that contains a clawback agreement and order pursuant to Federal Rule of Evidence 502(d) is appropriate in this case. The Parties have incorporated these provisions in a proposed Protective Order attached as Exhibit C to this Joint Report.

10. Whether Any Other Orders Should be Entered by the Court Pursuant to Rule 26(c) or 16(b), (c).

The Parties are not asking the Court to enter any orders besides those already discussed in this Joint Report.

11. The expected length of trial and whether it will be to a jury or the bench.

A jury demand was timely made in this action upon filing. The Parties estimate that the expected length of trial will be at least fifteen days. Due to difficulty in accurately gauging the length of trial at this early stage in the proceedings, the Parties respectfully request to supplement this response after the close of discovery.

12. The names of the attorneys who will appear on behalf of the parties at the Management Conference (the appearing attorney must be an attorney of record and have full authority to bind the client).

At least one attorney with authority to bind the client will attend in-person for each party.

The other counsel listed here will, with the Court's permission, attend by phone.

Relator	**Robert E. Barnes, Esq. (admitted *pro hac vice*)** **Lexis Anderson, Esq.** BARNES LAW 700 South Flower Street, Suite 1000 Los Angeles, California 90017 Telephone: (310) 510-6211 Email: robertbarnes@barneslawllp.com Email: lexisanderson@barneslawllp.com
Pfizer Inc.	**Carlton E. Wessel (admitted *pro hac vice*)** DLA Piper US LLP 500 Eighth Street, NW Washington, DC 20004 Telephone: (202) 799-4000 Email: Carlton.Wessel@us.dlapiper.com **Andrew J. Hoffman (admitted *pro hac vice*)** DLA Piper US LLP 2000 Avenue of the Stars Suite 400, North Tower Los Angeles, CA 90067-4704 Telephone: (310) 595-3010 Email: Andrew.Hoffman@us.dlapiper.com **Meagan Self** DLA Piper US LLP 1900 North Pearl Street, Suite 2200 Dallas, Texas 75201 Telephone: (214) 743-4556 Email: Meagan.Self@us.dlapiper.com **Tommy L. Yeates** MOORE LANDREY, LLP 905 Orleans Street Beaumont, Texas 77701 Telephone: (409) 835-3891 Email: tyeates@moorelandrey.com

Ventavia Research Group, LLC	**Taryn McDonald** **Andrew Guthrie** HAYNES AND BOONE, LLP 2323 Victory Avenue, Suite 700 Dallas, Texas 75219 Telephone: (214) 651-5584 Email: taryn.mcdonald@haynesboone.com Email: andrew.guthrie@haynesboone.com
ICON plc	**Elai Katz (admitted *pro hac vice*)** **Peter J. Linken (admitted *pro hac vice*)** CAHILL GORDON & REINDEL LLP 32 Old Slip New York, NY 10005 Telephone: (212) 701-3720 Email: Ekatz@cahill.com Email: Plinken@cahill.com **Scott L. Davis** HUSCH BLACKWELL, LLP 1900 N. Pearl Street, Suite 1800 Dallas, Texas 75201 Telephone: (214) 999-6184 Email: scott.davis@huschblackwell.com

13. Any other matters that counsel deem appropriate for inclusion in the Joint Conference Report.

The following motions are currently pending:

ECF No.	Pending Motions
37	Pfizer's Motion to Dismiss Relator's Amended Complaint
40	Pfizer's Motion to Stay Discovery
41	ICON's Motion to Stay Discovery and/or Notice of Joinder
42	Ventavia's Motion to Stay Discovery and/or Notice of Joinder

Date: May 17, 2022

Respectfully Submitted,

/s/ Robert E. Barnes
Robert E. Barnes, Esq.
Lexis Anderson, Esq.
Member of the Eastern District of Texas
BARNES LAW
700 South Flower Street, Suite 1000
Los Angeles, California 90017
Telephone: (310) 510-6211
Email: robertbarnes@barneslawllp.com
Email: lexisanderson@barneslawllp.com
Counsel for Relator Brook Jackson

/s/ Carlton E. Wessel
Carlton E. Wessel (admitted *pro hac vice*)
DLA Piper US LLP
500 Eighth Street, NW
Washington, DC 20004
Telephone: (202) 799-4000
Email: Carlton.Wessel@us.dlapiper.com

Andrew J. Hoffman (admitted *pro hac vice*)
DLA Piper US LLP
2000 Avenue of the Stars
Suite 400, North Tower
Los Angeles, CA 90067-4704
Telephone: (310) 595-3010
Email: Andrew.Hoffman@us.dlapiper.com

Meagan D. Self
DLA Piper US LLP
1900 North Pearl Street, Suite 2200
Dallas, Texas 75201
Telephone: (214) 743-4556
Email: Meagan.Self@us.dlapiper.com

Tommy L. Yeates
Moore Landrey, LLP
905 Orleans Street
Beaumont, Texas 77701
Telephone: (409) 835-3891
Email: tyeates@moorelandrey.com
Counsel for Defendant Pfizer Inc.

/s/ Stacy L. Brainin
Stacy L. Brainin
Andrew Guthrie
Taryn McDonald
Haynes and Boone, LLP
2323 Victory Avenue, Suite 700
Dallas, Texas 75219
Telephone: (214) 651-5584
Email: stacy.brainin@haynesboone.com
Email: andrew.guthrie@haynesboone.com
Email: taryn.mcdonald@haynesboone.com
Counsel for Defendant Ventavia Research Group, LLC

/s/ Scott L. Davis
Scott L. Davis
Husch Blackwell, LLP
1900 N. Pearl Street, Suite 1800
Dallas, Texas 75201
Telephone: (214) 999-6184
Email: scott.davis@huschblackwell.com

Jennifer Neiman Hinds (admitted *pro hac vice*)
HUSCH BLACKWELL, LLP
300 S. Grand Avenue, #1500
Los Angeles, CA 90071
Telephone: (213) 337-6567
Email: jennifer.hinds@huschblackwell.com

Elai Katz (admitted *pro hac vice*)
Peter J. Linken (admitted *pro hac vice*)
Tammy Roy (admitted *pro hac vice*)
CAHILL GORDON & REINDEL LLP
32 Old Slip
New York, NY 10005
Telephone: (212) 701-3720
Email: Ekatz@cahill.com
Email: Plinken@cahill.com
Email: Troy@cahill.com
Counsel for Defendant ICON, plc

CERTIFICATE OF SERVICE

I hereby certify that on May 17, 2022, a true and correct copy of the foregoing document was served upon all counsel of record via the Court's CM/ECF system in accordance with this Court's Local Rules.

/s/ Carlton E. Wessel
Carlton E. Wessel